K010623
Page 1 of 2

APR - 5 2001

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Bioject, Inc.
7620 SW Bridgeport Road
Portland, Oregon 97224

Phone: 800-683-7221 ext. 424
Fax: 503-620-6431
Email: nancy@bioject.com
Contact: Nancy J. Gertlar
Director, QA/RA
Date: March 1, 2001

B Device Information

Trade/Proprietary Name: Reconstitution Kit and Vial Connector

Common Name: Needle Free Fluid Transfer Device Accessory to a Syringe

Classification Name: Needle Free Fluid Transfer Device Accessory to a Syringe

Predicate Device(s):

- Vial Adapter K963012
- Clicker™ (cool.click™) K994384
- SeroJet™ K003908 (pending)

Device Description: The Reconstitution Kit and Vial Connector is the Bioject Vial Adapter attached to a commercially available syringe, now named the Reconstitution Kit, and packaged with a Vial Connector in sterile packaging for single time use.

Intended Use: The Reconstitution Kit and Vial Connector is intended to allow single access to drug vials for withdrawal of medications, withdrawal and transfer of diluents, and reconstitution and withdrawal of lyophilized medication without the use of needles.

C	Comparison of Required Technological Characteristics:	There is no change in the technological characteristics between the Bioject Vial Adapter, K963012 combined with the Vial Connector, K994384, when compared to the Reconstitution Kit and Vial Connector.
D	Summary and Conclusion of Non clinical and Clinical Tests	There is no change in the Summary and Conclusion of Non Clinical and Clinical Tests. All performance characteristics remain constant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Ms. Nancy Gertlar
Director of Regulatory Affairs & Quality Assurance
Biojet, Incorporated
7620 South West Bridgeport Road
Portland, Oregon 97224

Re: K010623
Trade Name: Reconstitution Kit & Vial Connector
Regulatory Class: II
Product Code: LHI
Dated: March 1, 2001
Received: March 2, 2001

Dear Ms. Gertlar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~new submission~~ K010623

Device Name: Reconstitution Kit and Vial Connector

Indications for Use:

- The Reconstitution Kit and Vial Connector is indicated for single access to drug vials for withdrawal of medication, withdrawal and transfer of diluents, and the reconstitution and withdrawal of lyophilized medications, without the use of needles. The Reconstitution Kit and Vial Connector may be used by physicians, nurses, and other practitioners who routinely administer injections, or by patients and other individuals authorized by their physicians to administer injections of prescribed medication.

Contraindications:

This product is not recommended for patients:

- Who are visually impaired,
- Who are not able to understand and follow the procedure for safe use of the device,
- Who are not willing to fully comply with the procedures of use of the device and with the recommended frequency for replacement of the disposable accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010623